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## DATA EVALUATION RECORD

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Tierney, D.P., et al, 2001. Exposure Analysis of Metolachlor in Community Water Systems in 27 States, 1993-2000, volume 1-5. Syngenta Crop Protection Report No. 2454-01. Unpublished study performed and submitted by Syngenta Crop Protection, Inc., Greensboro, NC and En fate, LLC, Plymouth, MN.

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### ABSTRACT

This study is a non-guideline study and therefore does not satisfy any of the requirements of Subdivision N. The registrant completed an assessment of eight years of Community Water System (CWS) data from 27 states which were analyzed for metolachlor. Several important points to note about this study follow:

1. Data aggregation presents a national picture of exposure to metolachlor in drinking water. However, metolachlor exposure in drinking water is expected to be more dependent on regional issues (i.e. climate, pesticide usage, agricultural patterns). EFED reevaluated the data for the top ten use states which indicates that the percentage of population exposed is highly dependent on the population being evaluated.

2. The study does not attempt to distinguish between exposure to racemic metolachlor and s-metolachlor. The analytical data from both periods does not distinguish between racemic metolachlor and s-metolachlor. No enantioselective monitoring data are available in the United States to document the effect on loadings of the transition from racemic metolachlor to s-metolachlor.
3. No degradates of metolachlor were analyzed in the CWS data. Degradates have been found at higher concentrations and frequencies than parent metolachlor in ground water.

The study does include useful information on the occurrence of metolachlor in CWS. According to the study authors, metolachlor was not detected in 97.7% of the 98,680 samples collected. Six percent of the 21,976 CWS reporting data had at least one detection of metolachlor. Using the PLEX database the authors report that no detections of metolachlor were present in the CWS data for locations serving a population of 124.2 million people (out of a total of 141.7 million, or 88%). According to the study, of the six percent of CWS with detections of metolachlor, 64 CWS had mean concentrations greater than 1.0 ppb and the maximum mean concentration was 7.4 ppb and the maximum single metolachlor concentration detected was 28.0 ppb from Missouri.

## MATERIALS AND METHODS

The study author requested data on the occurrence of metolachlor in CWS collected by states under the SDWA. Of the 32 states targeted by the study (representing greater than 95% of all metolachlor usage) 27 states responded with data on the occurrence of metolachlor in drinking water. Also included in the response was population data and source water type for each location. The study authors compiled the data submitted and completed exposure profiles for individual CWS locations, individual states, and the 27 state aggregate drinking water population. An annualized mean concentration was calculated for each individual CWS location. Individual mean concentrations were then used to estimate a state population weighted mean. Non detects were set at half the reported limit of quantitation (LOQ). The data did not include enantioselective information and therefore could not differentiate between racemic metolachlor and s-metolachlor. Also, the study did not include information on metolachlor degradates. Occurrence data consists of quarterly samples collected at each individual CWS location.

## RESULTS/DISCUSSION

The study presents the results of the analysis of population based exposure estimates calculated from surface and ground water monitoring data compiled from CWS data from 27 states. The database includes analytical results from 98,690 samples collected from 21,976 CWS locations in the 27 states. The monitoring data analyzed account for slightly greater than 60% of the CWS and 75% of the population from the 27 states. The 141.7 million people served by the CWS reporting data represent 68% of the population in the 27 states. Of the 98,680 samples collected, 97.7% were reported as non-detections.

It is worth noting that detection limits varied from state to state and that some data were not

included in the subsequent analysis. A total of 9,207 samples results from Alabama, California, Colorado, Indiana, and North Carolina were not used because a LOQ could not be determined. A total of 343 samples results were not used from Colorado and Iowa because the LOQ was reported to be greater than the HAL (100 ppb).

The authors report that of the 141.7 million people served by the CWS included in the study, 124.2 million (88%) had no detections of metolachlor. Approximately 12.3 million people (9%) were exposed to metolachlor concentrations above 1.0 ppb but less than 100 ppb. The maximum mean metolachlor concentration calculated by the study authors was 7.4 ppb and the maximum single metolachlor concentration detected was 28.0 ppb from Missouri (343 samples results were not used from Colorado and Iowa because the LOQ was reported to be greater than the HAL 100 ppb).

EFED reevaluated the data for the top ten use states (Table 2, page 17 of 1771 of study). The table below presents a summary of the data taken from the study (Tables 1 through 54 in Appendix B of the study, pages 47 through 134). The analysis of the data for the top ten states focused on the frequency of detection data and the percentage of population in each state exposed to metolachlor at concentrations above the LOQ. In the top use state of Iowa, greater than 42% of surface water samples and 21% of all samples contained metolachlor at concentrations above the LOQ. The analysis reveals that for the top ten states, 10.9 % of the population (6,869,782 people) are exposed to metolachlor above the LOQ. Further, focusing on the top five use states reveals that 18.0% of the population (4,660,204 people) are exposed to metolachlor above the LOQ. Finally, for the top state of Iowa, nearly 33% of the population (797,773 people) are exposed to concentrations of metolachlor above the LOQ.

This type of analysis indicates that the percentage of population exposed is highly dependent on the population being evaluated. Without the usage information for metolachlor (which was summarized in the study but not provided), it is impossible to determine the distribution of metolachlor use within the 27 states analyzed by the study authors.

Rank	State	Frequency of Detections in Surface Water (%)	Frequency of Detections in Ground Water (%)	Frequency of Detections in Other (%)	Frequency of Detections - Total (%)	Total Population in State	Total Population Exposed to Detections Above the LOQ	Percent of Total Population Exposed to Detections Above the LOQ
1	Iowa	42.1	15.1	36.1	21.1	2,926,324	797,773	32.89
2	Illinois	15.2	0.4	9.3	4.5	12,419,293	1,137,471	10.57
3	Nebraska	5.9	1.6	1.9	1.7	1,711,263	653,068	47.14
4	Kansas	32.1	6.4	31.2	19.5	2,688,418	763,425	39.98
5	Indiana	11.5	0.6	3.5	2.1	6,080,485	1,308,467	41.79
6	Ohio	20.6	0.0	15.4	8.4	11,353,140	1,928,045	19.61
7	Missouri	3.6	0.0	2.0	1.5	5,595,211	200,187	9.59

Rank	State	Frequency of Detections in Surface Water (%)	Frequency of Detections in Ground Water (%)	Frequency of Detections in Other (%)	Frequency of Detections - Total (%)	Total Population in State	Total Population Exposed to Detections Above the LOQ	Percent of Total Population Exposed to Detections Above the LOQ
8	Wisconsin	0.0	0.8	0.0	0.8	5,363,675	17,255	0.52
9	Minnesota	0.0	0.2	1.6	0.3	4,919,479	12,572	0.33
10	Michigan	0.9	0.0	2.4	0.2	9,938,444	51,519	0.72
Totals						62,995,732	6,869,782	10.9

### DEFICIENCIES/DEVIATIONS

1. It is important to note that the analysis is based on quarterly samples and does not represent a targeted sampling program. Typically, a targeted sampling program would be focused on more samples collected within a seasonal or agricultural window in order to capture as much of the peak runoff associated with pesticide usage. CWS data is not targeted in this manner and is likely to miss the peak concentrations and to under predict the long term (chronic) exposure.
2. The report includes a large volume of data which has not been summarized by the authors. The authors have summarized the aggregate exposure estimates calculated from the entire 27 state dataset. State by State summaries are presented in Appendix B but are not discussed in the report. A narrative summary of state occurrence data and the effect on state populations exposed would have been useful to fully characterize the data.
3. Use information for metolachlor was summarized in the study but not reported. It would be instructive to see the use data ranked in order to determine whether particular states (i.e. the 10 highest use states) should be evaluated as well.
4. It is also important to note that the data does not include degradate analysis. This is particularly important for the ground water portion of the study. Data from other monitoring studies (NAWQA) and the two PGW studies suggest that degradates occur in ground water at a much higher concentration and frequency than parent metolachlor.
5. Finally, the analytical data does not include enantioselective information and therefore could not differentiate between racemic metolachlor and s-metolachlor.. Without data which distinguishes between the enantiomers, it is impossible to say with any confidence that the concentrations in surface water are reflective of s-metolachlor use.

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Pages 5 through 13 are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
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